



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

16/SEP/2009

MEMORANDUM

Subject: Name of Pesticide Product: Difethialone Block 0707
EPA File Symbol: 7173-EII
DP Barcode: D365707
Decision No.: 408300
Action Code: R310
PC Code: 128967 Difethialone

From: Rick J. Whiting, Biologist
Technical Review Branch (TRB)
Registration Division (7505P)

R. Whiting *M. Haslin*
T.L. Toxicology

To: Jennifer Gaines / John Hebert, RM Team 07
Insecticide – Rodenticide Branch
Registration Division (7505P)

Applicant: Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

FORMULATION FROM LABEL:

Active Ingredient(s):
128967 Difethialone (CAS No. 104653-34-1)

% by wt
0.0025

Inert Ingredient(s):

99.9975
Total: 100.0000%

Difethialone (PC Code 128967)
EPA File Symbol 7173-EII Difethialone Block 0707

ACTION REQUESTED: The Risk Manager requests: ""This is a data waiver request submitted by the registrant in connection with the registration of 7173-EII. This should have been included in the Bean sent on April 27, so please include this in your review. The product is a [REDACTED] block, thus they are requesting a waiver of the acute inhalation toxicity data.""

BACKGROUND: Liphatech, Inc. has submitted a Basic and three (A, B, C) Alternate Formulation CFS dated March 26, 2009, a data matrix, a data waiver request for the acute inhalation study and a proposed label to support the registration of Difethialone Block 0707, EPA File Symbol 7173-EII. The provided data matrix cites five acute toxicity studies with MRID numbers 451796-01 thru -05. After searching the OPP electronic databases, TRB was unable to locate reviews for these studies. Therefore, TRB will review these studies as part of this action.

The following is from the registrant's acute inhalation data waiver request dated March 26, 2009:

Acute inhalation toxicity data is required if the product consists of, or under conditions of use will result in, an inhalable material (CFR 158.340 data table note 16).

The subject of this waiver request is a [REDACTED] block, which is not friable and will not produce respirable particulates during normal handling and use. A similar waiver has been granted for similar [REDACTED] block products (such as EPA Registration Numbers 7173-236 and 7173-239.)

Therefore, we request a waiver of the acute inhalation toxicity data requirement, and assignment of this product to toxicity category III for acute inhalation toxicity.

COMMENTS AND RECOMMENDATIONS:

1. The five studies have been reviewed and classified as Acceptable.
2. TRB has reviewed the registrant's acute inhalation study waiver request and agrees that the requirement for an acute inhalation study can be waived. As requested by the registrant, a Toxicity Category of III will be used in the acute toxicity profile below.
3. The acute toxicity profile for Difethialone Block 0707, EPA File Symbol 7173-EII, is as follows:

Acute oral toxicity	IV	Acceptable	MRID 45179601
Acute dermal toxicity	III	Acceptable	MRID 45179602
Acute inhalation toxicity	III	Waived	
Primary eye irritation	IV	Acceptable	MRID 45179603
Primary skin irritation	IV	Acceptable	MRID 45179604
Dermal sensitization	Negative	Acceptable	MRID 45179605

4. Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 007173-00288

PRODUCT NAME: Difethialone Block 0707

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Avoid breathing dust.

First Aid:

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move the person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: technical information on symptomatology; use of supportive treatments to maintain life functions; medicine that will counteract the specific physiological effects of the pesticide; company telephone number to specific medical personnel who can provide specialized medical advice.

NOTE TO PHYSICIAN: Note to CRM/PM/Registrant: The proposed label should contain a "Note to Physician" which addresses the presence of an anticoagulant. The following statements are suggested types of information that may be included, if applicable:

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. In addition, TRB noted that the registrant has included additional Precautionary and First Aid statements. TRB finds this additional labelling information acceptable.

6. The Basic and Alternate Formulation CSFs (dated March 26, 2009) for the proposed product have been reviewed and accepted by the TRB Product Chemistry Team (H. Mukhoty; D364479; 20/AUG/2009).

Reviewer: Rick J. Whiting
Risk Manager (EPA): 07

Date: September 16, 2009

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100; 81-1

TEST MATERIAL: Difethialone Mini Blocks (Difethialone – 0.002644%; Lot.No. 16593; yellow solid)

CITATION: Glaza, S. (1993) Acute Oral Toxicity Study (Limit Test) of Difethialone Mini Blocks in Rats: Lab Project Number: HWI 30702260. Unpublished study prepared by Hazleton Wisconsin, Inc. 22 p. November 24, 1993. MRID 45179601

SPONSOR: LipaTech, Inc., Milwaukee, WI.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 4517601), young adult Crl:CDBR strain rats (5/sex; age: not reported; body weight: males: 244-261 g and females: 217-233 g; source: Charles River Laboratories, Inc., Portage, MI) were given a single oral dose of 5000 mg/kg of Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid). The test material was finely ground and mixed with distilled water to a concentration of 0.25 g/ml. An individual dose was calculated for each animal based on its body weight and administered by gavage at a volume of 20 ml/kg of body weight. Clinical observations and mortality checks were conducted at approximately 1, 2.5 and 4 hours after dosing. Additional clinical observations and twice a day mortality were conducted daily thereafter for 21 days. Body weights were determined before dosing and at weekly intervals throughout the study. At study termination, all animals were euthanized, subjected to an abbreviated gross necropsy examination, and any abnormalities were recorded.

All animals survived and gained body weight during the study. No clinical signs were noted for any animal over the course of the study. No gross abnormalities were noted at necropsy.

Oral LD₅₀ Males > 5000 mg/kg bw
Oral LD₅₀ Females > 5000 mg/kg bw
Oral LD₅₀ Combined > 5000 mg/kg bw

Based on the Oral LD₅₀, Difethialone Mini Blocks is classified as EPA Toxicity Category IV.

This acute oral study is classified as Acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; 81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Statistics: The oral LD₅₀ was calculated using the limit dose.

A. Mortality: There were no deaths.

B. Clinical observations: No clinical signs were noted for any animal over the course of the study.

C. Gross Necropsy: No gross abnormalities were noted at necropsy.

D. Reviewer's Conclusions: TRB agrees with the study author's conclusions. Based on the oral LD₅₀, Difethialone Mini Blocks is classified as EPA Toxicity Category IV.

E. Deficiencies: The age of the test animals should have been provided.

Reviewer: Rick J. Whiting
Risk Manager (EPA): 07

Date: September 16, 2009

STUDY TYPE: Acute Dermal Toxicity - Rabbit; OPPTS 870.1200; 81-2

TEST MATERIAL: Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid)

CITATION: Glaza, S. (1993) Acute Dermal Toxicity Study (Limit Test) of Difethialone Mini Blocks in Rabbits: Lab Project Number: HWI 30702261. Unpublished study prepared by Hazleton Wisconsin, Inc. 23 p. December 3, 1993. MRID 45179602

SPONSOR: LipaTech, Inc., Milwaukee, WI.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45179602), young adult Hra:(NZW)SPF rabbits (5/sex; age: not reported; body weight: males: 2149-2387 g and females: 2035-2227 g; source: Hazleton Research Products, Inc., Kalamazoo, MI) were dermally exposed to Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid) for 24 hours. Prior to application, the test material was ground to a fine powder and an individual dose was calculated and weighed out based on each animal's body weight on the day of the test material administration. Each dose was thoroughly moistened with 0.9% saline before application. The test material was applied to the intact skin on each animal's back at a dose level of 2000 mg/kg. The area of application was covered with a 10-cm x 10-cm gauze patch secured with paper tape and overwrapped with Saran Wrap® and Elastoplast® to provide an occlusive dressing. Collars were used to restrain the test animals during the exposure period. After the exposure period, the restraining collars and bandages were removed and the test sites were washed using tap water and disposable towels.

Clinical observations and mortality checks were conducted at approximately 1, 2.5 and 4 hours after dosing. Additional clinical observations and twice a day mortality were conducted daily thereafter for 21 days. Body weights were determined before dosing and at Days 7, 14 and 21. The initial dermal irritation reading was made approximately 30 minutes after removal of the test material according to the Draize method. Subsequent readings of dermal irritation were made on Days 3, 7, 10, 14 and 21. At study termination, all animals were euthanized, subjected to an abbreviated gross necropsy examination, and any abnormalities were recorded.

All animals survived and gained body weight during the study. No clinical signs were noted for any animal over the course of the study. Dermal irritation consisted of slight to moderate erythema in all animals on Day 1 and in two animals on Day 3. No other dermal irritation was observed. The following is from the pathology report (page 12 of the study): "At necropsy, the subcutaneous tissue of the treated skin in three females had multiple dark red areas of variable size. These lesions are suggestive of trauma and was possibly treatment-related. There were no visible lesions in the remaining animals."

Dermal LD₅₀ Males > 2000 mg/kg bw
Dermal LD₅₀ Females > 2000 mg/kg bw
Dermal LD₅₀ Combined > 2000 mg/kg bw

Based on the LD₅₀, Difethialone Mini Blocks is classified as EPA Toxicity Category III.

This acute dermal study is classified Acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; 81-2) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
2000	0/5	0/5	0/10

A. Mortality: There were no deaths.

B. Clinical observations: No clinical signs were noted for any animal over the course of the study.

C. Dermal observations: Dermal irritation consisted of slight to moderate erythema in all animals on Day 1 and in two animals on Day 3. No other dermal irritation was observed.

D. Gross Necropsy: The following is from the pathology report (page 12 of the study): "At necropsy, the subcutaneous tissue of the treated skin in three females had multiple dark red areas of variable size. These lesions are suggestive of trauma and was possibly treatment-related. There were no visible lesions in the remaining animals."

D. Reviewer's Conclusions: TRB agrees with the study author's conclusions. Based on the LD₅₀, Difethialone Mini Blocks is classified as EPA Toxicity Category III.

E. Deficiencies: The age of the test animals should have been provided.

Reviewer: Rick J. Whiting
Risk Manager (EPA): 07

Date: September 16, 2009

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400; 81-4

TEST MATERIAL: Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid)

CITATION: Glaza, S. (1993) Primary Eye Irritation Study (Limit Test) of Difethialone Mini Blocks in Rabbits: Lab Project Number: HWI 30702263. Unpublished study prepared by Hazleton Wisconsin, Inc. 23 p. November 19, 1993. MRID 45179603

SPONSOR: LipaTech, Inc., Milwaukee, WI.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45179603), Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid) was instilled into the conjunctival sac of the right eye of young adult Hra: (NZW)SPF rabbits (3/sex; weight: 2265-2415 g; source: Hazleton Research Products, Inc., Kalamazoo, MI). The untreated left eye served as a control. Prior to instillation, the test material was ground into a fine powder. A bulk density determination of the test material was then made to determine the weight equivalent of a 0.1 ml dose. An individual dose of 0.05 g was weighed out for each animal based on the test material bulk density of 0.53 g/ml. Ocular irritation was evaluated in accordance to Draize technique (1975) at 1, 24, 48 and 72 hours after instillation. A sodium fluorescein examination was used to aid in revealing possible corneal injury at 72 hours.

There was no corneal opacity or iritis observed in any treated eye during the study. Conjunctival redness (score 2) was observed in 5/6 eyes at 1 hour. No “positive scores” for conjunctival chemosis and discharge were observed in any treated eye during the study. All ocular irritation was resolved by 72 hours.

In this study, the formulation was minimally irritating to the eye. Difethialone Mini Blocks is classified as EPA Toxicity Category IV for primary eye irritation.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; 81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
Corneal Opacity	0/6	0/6	0/6	0/6
Iritis	0/6	0/6	0/6	0/6
Conjunctivae:				
Redness*	5/6	0/6	0/6	0/6
Chemosis*	0/6	0/6	0/6	0/6
Discharge*	0/6	0/6	0/6	0/6

*Score of 2 or more required to be considered "positive."

A. Observations: There was no corneal opacity or iritis observed in any treated eye during the study. Conjunctival redness (score 2) was observed in 5/6 eyes at 1 hour. No "positive scores" for conjunctival chemosis and discharge were observed in any treated eye during the study. All ocular irritation was resolved by 72 hours.

B. Results: Difethialone Mini Blocks was minimally irritating.

C. Reviewer's Conclusions: TRB agrees with the study author's conclusions. Difethialone Mini Blocks is classified as EPA Toxicity Category IV.

D. Deficiencies: None.

Reviewer: Rick J. Whiting
Risk Manager (EPA): 07

Date: September 16, 2009

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500; 81-5

TEST MATERIAL: Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid)

CITATION: Glaza, S. (1993) Primary Dermal Irritation Study (Limit Test) of Difethialone Mini Blocks in Rabbits: Lab Project Number: HWI 30702262. Unpublished study prepared by Hazleton Wisconsin, Inc. 21 p. December 3, 1993. MRID 45179604

SPONSOR: LipaTech, Inc., Milwaukee, WI.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45179604), young adult Hra: (NZW)SPF rabbits (3/sex; weight: 2420-2622 g; source: Hazleton Research Products, Inc., Kalamazoo, MI) were dermally exposed to Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid). Prior to treatment, the test material was ground to a fine powder. The ground test material was applied to the intact skin on each test animal's back (approximate exposure area of 6.25 cm²) in the amount of 0.5 g and was moistened with 0.9% saline. The test area was covered with a 2.5-cm x 2.5-cm gauze patch secured with paper tape, loosely overwrapped with Saran Wrap® and Elastoplast® to provide an occlusive dressing. Collars were not used to restrain the test animals during the 4-hour exposure period. After the exposure period, the patches were removed and the test sites were washed using tap water and disposable towels. Any residue test material was removed from the test sites as thoroughly as possible without irritating the skin. Approximately 30 minutes after removal of the test material, the degree of dermal irritation at each test site was scored according to the Draize technique (1959) [recorded as the 4-hour score]. Subsequent examinations were made at 24, 48 and 72 hours.

Very slight erythema (score 1) was observed in 6/6 animals at 1 hour with clearance by 24 hours. No other dermal irritation was observed.

In this study, the formulation was non-irritating. Difethialone Mini Blocks is classified as EPA Toxicity Category IV for primary dermal irritation. Primary Irritation Index (PII) = 0.25.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; 81-5) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal No.	Sex	Hours After Patch Removal			
		4	24	48	72
F48167	F	1/0	0/0	0/0	0/0
F48168	F	1/0	0/0	0/0	0/0
F48169	F	1/0	0/0	0/0	0/0
F48170	M	1/0	0/0	0/0	0/0
F48171	M	1/0	0/0	0/0	0/0
F48172	M	1/0	0/0	0/0	0/0

A. Observations: Very slight erythema (score 1) was observed in 6/6 animals at 1 hour with clearance by 24 hours. No other dermal irritation was observed.

B. Results: Primary Dermal Irritation Index (PDII) = 0.25

C. Reviewer's Conclusions: TRB agrees with the study author's conclusions. Difethialone Mini Blocks is classified as EPA Toxicity Category IV.

D. Deficiencies: None.

Reviewer: Rick J. Whiting
Risk Manager (EPA): 07

Date: September 16, 2009

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; 81-6

TEST MATERIAL: Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid)

CITATION: Glaza, S. (1993) Dermal Sensitization Study of Difethialone Mini Blocks in Guinea Pigs-Closed Patch Technique: Lab Project Number: HWI 30702264. Unpublished study prepared by Hazleton Wisconsin, Inc. 29 p. December 27, 1993. MRID 45179605

SPONSOR: LipaTech, Inc., Milwaukee, WI.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 45179605) with Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid), 28 young adult male Crl:(HA)Br guinea pigs (weight: 354-490 g; source: Charles River Laboratories, Inc., Portage, MI) were tested using the closed patch technique. The test animals were divided into four groups consisting of an irritation screening group of four animals, a test group of ten animals, a naïve control group of ten animals and a positive control group of four animals. Due to the lack of irritation or toxicity observed in the irritation screening study, the ground test material was administered as a 0.2 g dose moistened with deionized water for the induction phase and the challenge application.

The following is from pages 8 and 9 of the study:

“Induction Phase: On the day of test material application, the hair was removed from the backs of each animal in the test and positive control groups with electric clippers. The test material was applied to each animal in the test group by placing 0.2 g of test material (moistened with deionized water) on an adhesive patch (Hill Top Chamber®, 25-mm diameter) and placing the patch on the induction site along the anterior left flank. The patch was covered with dental dam and overwrapped with Elastoplast® tape. The dressing remained in place for a period of 6 hours after which it was removed and the induction site wiped with a wet disposable paper towel. The positive control material [0.3% w/v 2,4-dinitrochlorobenzene (DNCB) in 80% v/v ethanol in deionized water] was administered as a 0.4 mL dose to the positive control animals in the same manner used for the test material. The animals in the test and positive control groups received one application per week for 3 weeks for a total of three applications. Due to the strong irritation present in the induction site of the positive control animals, the third induction dose for these animals was applied to an induction site slightly posterior to the initial site. The naïve control animals were not treated during this phase of the study.”

“Challenge Phase: Two weeks following the administration of the third induction dose, a challenge dose of 0.2 g of test material was administered along the anterior right flank of the test group animals in the same manner as during the induction phase of the study. At this time the 10 naïve (previously untreated) control animals were also treated in the same manner with a challenge application of the test material. The positive control material was administered at a concentration of 0.1% w/v in acetone. The method used for the positive control group was the

same as that of the test group with the exception that the test sites were rinsed with tap water after patch removal.”

“Approximately 3 hours before the 24-hour examination following the irritation screening and challenge applications, the test sites of the respective animals were depilated by applying Neet® depilatory for approximately 20 minutes, which was then washed off with lukewarm water. The respective application sites were examined and scored for dermal reactions according to the Buehler (1980) scoring scale at approximately 24 and 48 hours following the irritation screening, induction, and challenge applications.”

“Clinical observations were conducted daily throughout the study. Body weights on the definitive study animals were taken on Day 1, at weekly intervals throughout the study, and at termination of the experimental phase.”

There were no observed dermal reactions in the test group of animals during the induction or challenge phase of the study. No dermal reactions were observed in the naive control animals during the challenge application of the test material.

Based on the results of this study, Difethialone Mini Blocks is not considered to be a dermal sensitizer.

This study is classified as Acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; 81-6) in the Guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE:

A. Induction: On the day of test material application, the hair was removed from the backs of each animal in the test and positive control groups with electric clippers. The test material was applied to each animal in the test group by placing 0.2 g of test material (moistened with deionized water) on an adhesive patch (Hill Top Chamber®, 25-mm diameter) and placing the patch on the induction site along the anterior left flank. The patch was covered with dental dam and overwrapped with Elastoplast® tape. The dressing remained in place for a period of 6 hours after which it was removed and the induction site wiped with a wet disposable paper towel. The positive control material [0.3% w/v 2,4-dinitrochlorobenzene (DNCB) in 80% v/v ethanol in deionized water] was administered as a 0.4 mL dose to the positive control animals in the same manner used for the test material. The animals in the test and positive control groups received one application per week for 3 weeks for a total of three applications. Due to the strong irritation present in the induction site of the positive control animals, the third induction dose for these animals was applied to an induction site slightly posterior to the initial site. The naive control animals were not treated during this phase of the study.

B. Challenge: Two weeks following the administration of the third induction dose, a challenge dose of 0.2 g of test material was administered along the anterior right flank of the test group animals in the same manner as during the induction phase of the study. At this time the 10 naive (previously untreated) control animals were also treated in the same manner with a challenge application of the test material. The positive control material was administered at a concentration of 0.1% w/v in acetone. The method used for the positive control group was the same as that of the test group with the exception that the test sites were rinsed with tap water after patch removal.

C. Naive Controls: At this time the 10 naive (previously untreated) control animals were also treated in the same manner with a challenge application of the test material.

II. RESULTS and DISCUSSION:

A. Reactions and duration: There were no observed dermal reactions in the test group of animals during the induction or challenge phase of the study. No dermal reactions were observed in the naive control animals during the challenge application of the test material.

B. Positive control: The positive control animals were considered to have been sensitized because of the moderate to strong dermal reactions they exhibited to the 0.1% w/v concentration of DNCB in acetone at challenge.

C. Reviewer's Conclusions: TRB agrees with the study author that Difethialone Mini Blocks is not a dermal sensitizer.

D. Deficiencies: None.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D365707
2. **PC CODE:** 128967
3. **CURRENT DATE:** 16/SEP/2009
4. **TEST MATERIAL:** Difethialone Mini Blocks (Difethialone – 0.002644%; Lot No. 16593; yellow solid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat Hazleton Wisconsin, Inc. HWI 30702260 / November 24, 1993	45179601	LD ₅₀ > 5000 mg/kg (males and females)	IV	A
Acute dermal toxicity / rabbit Hazleton Wisconsin, Inc. HWI 30702261 / December 3, 1993	45179602	LD ₅₀ > 2000 mg/kg (males and females)	III	A
Primary eye irritation / rabbit Hazleton Wisconsin, Inc. HWI 30702263 / November 19, 1993	45179603	Conjunctival redness in 5/6 eyes at 1 hour; no “positive scores” at 24 hours	IV	A
Primary dermal irritation / rabbit Hazleton Wisconsin, Inc. HWI 30702262 / December 3, 1993	45179604	Very slight erythema at 1 hr; all irritation resolved by 24 hrs	IV	A
Dermal sensitization / guinea pig Hazleton Wisconsin, Inc. HWI 30702264 / December 27, 1993	45179605	Negative	---	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived